Canada's Drug and Health Technology Agency

Abiraterone Acetate and Prednisone

FMEC Responses to Questions From the Drug Programs

Table 1: Response Summary

Drug program implementation questions	FMEC response
Considerations for initiation of therapy	
Is the definition of high-risk disease that was used in the clinical trial consistent with how high-risk nmPC is defined in the clinical setting?	FMEC agrees with the clinical expert that the definition of "high-risk nmPC" in the STAMPEDE trial is different than that used in the Canadian clinical setting. In the Canadian setting, the patients would be considered more advanced and represent the patient population with very high-risk nmPC. The differences in definition of high-risk nmPC between Canadian clinical practice and the STAMPEDE trial are reflected in the initiation criteria of the Reimbursement Recommendation.
If a patient completes 2 years of abiraterone acetate and prednisone therapy and then subsequently relapses, what would be an appropriate time frame that must elapse between the last dose of abiraterone and the restart of abiraterone?	FMEC agrees with the clinical expert and recommends relapse of 6 months or longer from the completion of abiraterone as an appropriate interval for re-treatment.
Generalizability	
For patients who start on ADT: What would be an appropriate time frame for adding abiraterone acetate and prednisone to ADT (within 3 months from starting)?	FMEC agrees with the clinical expert that abiraterone treatment intensification should occur within 3 months of initiating ADT.

ADT = androgen deprivation therapy; FMEC = CADTH Formulary Management Expert Committee; nmPC = nonmetastatic prostate cancer.